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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,681	08/18/2003	Orville G. Kolterman	254/057CON	4614

44638 7590 12/14/2007

Intellectual Property Department
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121

EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
12/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,681	KOLTERMAN ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-30 and 38-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-30 and 38-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 1-23, 31-37, and 60-69 have been cancelled.

Claims 24-30, and 38-59 are currently pending.

Claims 24-30 and 38-59 are being examined in this application.

Election/Restriction

2. Applicant's election with traverse of 25,28,29 tri-pro human amylin as the elected species in the correspondence dated 10/29/04 is as previously acknowledged and was previously made final.

Priority

3. This application is a CONTINUATION of U.S. Patent Application No. 09/576,062 (filed 5/22/2000), which is now a US PATENT, 6,608,029 (8/19/2003). The U.S. Patent Application No. 09/576,062 is a CONTINUATION of U.S. Patent Application Nos. 08/302,069 (filed 9/7/1994), which is now a US PATENT, 6,114,304 (9/5/2000). The U.S. Patent Application No. 08/302,069 is a CIP of U.S. Patent Application Nos. 08/118,381 (filed 9/7/1993), which is now abandoned.

Claim Objection(s) / Rejections Withdrawn

4. In light of applicants amendments to the claims to recite the specific amino acid sequences for "amylin agonist analogues", the following claim rejections are withdrawn:

A.) Claims 24 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarantakis et al (US 4,451,394; 05/29/1984; cited previously).

B.) Claims 24 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

C.) Claims 24 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment of reducing postprandial rise in blood glucose using peptides with SEQ ID Nos: 1, 3, 6, 8-10, 31, 38 and 41-49, does not reasonably provide enablement for using any other peptides that binds to an amylin receptor for treatment of blood glucose levels.

D.) Claims 24-30 and 38-59 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. However, new issues arise under 35 U.S.C. 112, second paragraph, due to applicant's amendments of the claims. (See the rejection set forth below).

New Claim Objection(s) and Rejection(s)

Claim Rejections - 35 USC § 112

Second paragraph of 35 U.S.C. 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 24-30 and 38-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites "amylin agonist analogue is a peptide having **an** amino acid sequence selected from the group consisting..." which the term "an" renders the claim unclear. The claim can be interpreted to comprise various different sequences such as partial or fragments of the amino acid sequences listed in the claims. Amending the claim language to recite "a peptide having **the** amino acid sequence..." would overcome the instant rejection.

Claims 24 and 56 recite SEQ ID NO: 31, which has a "X" in position 2, and another "X" in position 7, and does not recite a "Y" residue in the sequence. However, the instant claim provides limitations for both a "X" and a "Y" residue. Thus, it is not clear what specific sequence is constituted by the instant claimed SEQ ID NO: 31.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

'411

8. Claims 24-30 and 38-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 5,686,411 (hereinafter referred to as the '411 patent; cited in IDS). This rejection is necessitated by applicants' amendments to the claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention of the '411 patent reads on the instant claimed invention.

The '411 patent claims (e.g. claims 1-12 and 30-37) "A method for treatment of diabetes mellitus in a mammal comprising the administration to said mammal of a therapeutically effective amount of an agonist analogue of amylin according to claim 3", which amylin of 3 read on the amino acid sequences of the instant claim 24. The method of treating "diabetes mellitus" also reads on the method of "reducing or moderating a postprandial rise in plasma glucose" of the instant claims 24-30 and 38-59, because "postprandial rise in plasma glucose" is one of the symptoms of "diabetes mellitus" as evidenced by the instant specification (e.g. [0025]).

'238

9. Claims 24-30 and 38-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 7,271,238 (hereinafter referred to as the '238 patent). This rejection is necessitated by applicants' amendments to the claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention of the '238 patent reads on the instant claimed invention.

The '238 patent claims (e.g. claims 1, 5, 8, and 9) "A method for treatment of diabetes mellitus in a mammal comprising administering the agonist analog of amylin claim 1 to the mammal", which the "agonist analog of amylin" of claims 1 and 7 read on the amino acid sequences of the instant claims 24. The method of treating "diabetes mellitus" also reads on the method of "reducing or moderating a postprandial rise in plasma glucose" of the instant claims 24-30 and 38-59, because "postprandial rise in plasma glucose" is one of the symptoms of "diabetes mellitus" as evidenced by the instant specification (e.g. [0025]).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
11/30/07

/Jon D. Epperson/
Primary Examiner, AU 1639